## REMARKS/ARGUMENTS

Claims 1-7 are pending in this application. Claims 1-7 are rejected in the Office action of October 6, 2004. In view of the arguments made herein, Applicants respectfully request reconsideration of these claims. Applicant also submits herewith a copy of the Declaration Under 37 CFR § 1.132 (hereinafter referred to as the "Schwendeman Declaration") that was originally submitted in the parent case.

**Rejections under 35 U.S.C. § 103(a)**

Claims 1-7 are rejected under 35 U.S.C. § 103(a) over Cleland *et al.* (US Pat. No. 5,63,605, hereinafter referred to as "Cleland.") Applicants respectfully disagree. Cleland does not teach or suggest a biodegradable polymeric system whose microclimate maintains a pH of greater than 3 during biodegradation of the polymeric system for at least 4 weeks. Cleland does not teach adding from 10% to 30% (w/w) of a pore-forming agent with the PLGA polymer solution to provide a resulting solution comprising the polymer and the pore-forming agent. Cleland does not teach or suggest the use of PEG, at a level of 10% to 30% (w/w) as a pore forming agent. Cleland does not teach or suggest the use of a poloxamer, at a level of 10% to 30% (w/w) as a pore-forming agent. Moreover, Cleland does not teach or suggest the unexpected result that addition of a specific amount of pore forming agent, 10% to 30%, as recited in the claim, to the polymer results in the polymer microclimate being maintained above pH 3 during biodegradation. See, Schwendeman Declaration, paragraph 6.

Nowhere in Cleland is the teaching or suggestion to add the specific amount of pore forming agent, 10% to 30% (w/w) claimed by Applicants. As Examiner notes, Cleland does suggest using PEG or poloxamer as an excipient. However, Cleland does not teach or suggest use of PEG or poloxamer at a level of 10% to 30% (w/w) based on polymer, which is the range necessary in order for the polymer microclimate to be maintained at a pH above 3 during biodegradation. (Schwendeman Declaration, paragraph 6.)

With respect to the pH range recited in Cleland, Cleland does teach a pH in the range from 5 to 8 (Cleland, column 9, lines 35-36), as noted by the Examiner. However, this pH is not the microclimate pH experienced during biodegradation. The pH in Cleland is the pH of the

antigen solution prior to encapsulation. Nothing in Cleland teaches or suggests microclimate pH of greater than 3 during biodegradation.

Moreover, nowhere does Cleland teach or suggest a method of preparing a biodegradable polymeric delivery system wherein the microclimate pH at greater than 3 during biodegradation. Nowhere does Cleland teach or suggest using from 10% to 30% of a pore-forming agent is necessary in order to achieve this effect. Nowhere does Cleland teach adding 10% to 30% (w/w) of PEG or poloxamer to the polymer in order to achieve this effect. Cleland does not teach or suggest all limitations of the claimed invention.

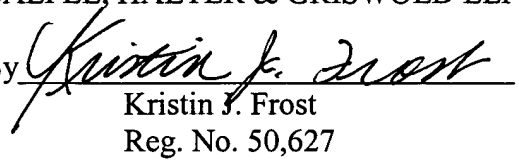
**Double Patenting**

Claims 1 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 22 of US Pat. No. 6,743,466. A terminal disclaimer is submitted herewith, thereby obviating the rejection.

In conclusion, in light of the Declaration submitted herewith and the remarks made herein, Applicants submit that claims 1-7 are now in condition for allowance. Prompt notice of such allowance is respectfully requested.

Respectfully submitted,

CALFEE, HALTER & GRISWOLD LLP

By 

Kristin J. Frost
Reg. No. 50,627
Tel.: (216) 622-8895